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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,873	SINGHAL ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/29/04, 05/31/05, 06/17/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "motion reduction element" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "motion reduction elements" 621. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement

drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 55 is objected to because of the following informalities: "the means for integrating means for receiving" in the first and second lines of the Claim appears to be a typographical error. The Examiner suggests changing the Claim to read, "the means for integrating comprises means for receiving" instead. Appropriate correction is required.

4. Claim 56 is objected to because of the following informalities: "motion" in the first line of the Claim appears to be a typographical error. The Examiner suggests changing the Claim to read, "method" instead. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 9, 20-21, and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Faltys et al. (U.S. 6,308,101) (herein Faltys). Faltys discloses a modular implantable medical device 170, each of the modules comprising a housing (see Faltys Abstract, lines 1-4 and column

23, lines 12-14) and a flexible overmold 174 that integrates the modules into a single structure and at least partially encapsulates each of the housings (see Faltys Fig. 3A, 3B, 4A, and 4B). Faltys also discloses that overmold 174 may be made from highly thermally conductive silicone rubber (see Faltys column 12, lines 32-34 and line 39).

7. As to Claim 9, The Examiner takes the position that the stiff noble metal wire coil 172 contained within overmold 174 (see Falyts Fig. 3A) is synonymous to a motion reduction element to reduce intermodular motion due to the Applicant's disclosure page 15, paragraph 60.

8. As to Claim 56, Faltys discloses a method of providing the modular implantable medical device in Claim 19 column 23, lines 8-24 and column 24, lines 1-24. It is inherent that the overmold 174 and the motion reduction element 172 were fabricated in addition to the plurality of modules and combined with the plurality of modules to construct the modular implantable medical device disclosed by Faltys.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys. Faltys differs from Claim 6 in that the non-elastomeric material disclosed is not one of a polysulfone and a polyurethane. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the non-elastomeric material one of a biocompatible polysulfone and a polyurethane, since it has been held to be within the general skill of a worker

in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

11. Claims 5, 7-8, 10-19, 22-26, 30-36, 37-43, 45-53, and 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys in view of Reischl et al. (U.S. 6,176,879) (herein Reischl). Faltys differs from Claims 5, 7-8, 32, 47-49, 57, 59, and 61 in that the flexible silicone overmold does not comprise a non-elastomeric second component that is located adjacent to side surfaces of at least one of the housings.

Reischl, however, discloses an implantable medical device that comprises an overmold 11 made of a first component 12 and a second component 13. The metal portion 13 is located adjacent to a side surface of electronic module 24 (see Reischl Figs. 1-3 and column 52-54) in order to provide an overmold design that is partially rigid (i.e. provides structural integrity) in order to reduce the mechanical stresses on the electrical components housed within the module and on the electrical connections (see Reischl, column 30-33). The Examiner takes the position that "adjacent" is synonymous with "close to or lying near" and makes reference to Fig. 2. The Examiner also takes the position that the disclosed medical implant of Reischl is analogous to the disclosed medical implant of Faltys because both have functional components separated into individual interconnected modules and both have a small profile with allows the device to better fit available body locations such as the cranium. Therefore, it would have been obvious to modify the elastomeric overmold of Faltys in view of Reischl to comprise an elastomeric first component that at least partially encapsulates each of the housings and a non-elastomeric second component that is located adjacent to side surfaces of at least one of the housings of the modules

in order to reduce the mechanical stresses on the components housed within the device and on the electrical connections.

12. Faltys differs from Claim 10 in that lead connection 224 module is located on the outside of the housing of module 210 and not within a the overmold. Reischl, however, discloses an implantable medical device that comprises an overmold 11 made of a first component 12 and a metal second component 13 and a lead connection module deployed within the first component to allow for transcutaneous data transmission (see Reischl column 3, lines 50-60). The disclosed energy storage device is considered to anticipate the claimed lead connection module because both electrically and mechanically couple lead 23 to the implantable device components. Therefore it would have been obvious to modify the device of Faltys in view of Reischl to include a lead connection module within the overmold to allow for transcutaneous data transmission.

13. The modified Faltys differs from Claims 11 and 38 in that the lead connection module is not deployed within the second component. It would have been obvious to one having ordinary skill in the art at the time the invention was made to move the lead connection module from the first to the metal second component of the overmold, since it has been held that rearranging parts of an invention involves only routine skill in the art.

14. Faltys differs from Claim 22 in that the overmold does not comprise a material that has a low thermal conductivity. Reischl, however, discloses an implantable medical device that comprises an overmold 11 made of a ceramic component 12 that has a low thermal conductivity and that is transparent to electrical, magnetic and electromagnetic fields (see Reischl column 3, lines 35-37). Therefore, it would have been obvious to modify the overmold of Faltys in view of

Reischl to comprise ceramic, which has low thermal conductivity to act as a shield of thermal energy generated within the modules.

15. As to Claim 23, 25, 37,and 51 Reischl discloses an overmold 11 that provides external lead management 25 for external leads 23 being routed away from the implantable medical device (see Reischl column 4, lines 12-23). The Examiner takes the position that a "pouch" is synonymous with a "sealed container" and lead management 25 is a "sealed container".

16. As to Claim 24 and 53, Reischl discloses a feed-through wire to electrically couple an external lead to an electronic component within the implantable medical device (see Reischl column 4, lines 12-23). It is inherent that a "feed-through" is accomplished via a groove or long narrow furrow or channel located within the overmold. The disclosed feedthrough is considered to anticipate the claimed groove because both allow components within the housing of the implantable medical device to be coupled to one or more leads or the like located outside the overmold of the device while maintaining the hermaticity of the device.

17. As to Claims 26 and 54, Reischl discloses a removal assist structure 25, adjacent and attachable to the over mold, capable of assisting in the removal of the implantable medical device (see Reischl Fig. 2). The Examiner takes the position that this structure 25 is identical to the structure disclosed by the Applicant. Reischl differs from Claims 26 and 54 in that the removal assist structure is not hermatically part of the overmold of the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the removal assist structure part of the overmold, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art.

18. As to Claim 30, Reischl discloses an implantable medical device implanted on a cranium of a patient comprising an overmold that includes a cap to cover a hole within a cranium. The Examiner takes the position that "a cap" is synonymous with "a device that covers" and the overmold of Reischl is a cap or device that covers a hole within a cranium (see Reischl Fig. 2).

19. The modified Faltys reference differs from Claim 34 in that the non-elastomeric material disclosed is not one of a polysulfone and polyurethane. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the non-elastomeric material on of a biocompatible polysulfone and a polyurethane, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

20. As to Claim 35 and 50, The Examiner takes the position that the stiff noble metal wire coil 172 contained within overmold 174 (see Faltys Fig. 3A and column 12, lines 64-67) is synonymous to a motion reduction element to reduce intermodular motion due to the Applicant's disclosure page 15, paragraph 60.

21. As to Claim 36, The Examiner takes the position that the previously modified Faltys reference includes motion reduction element 172 contained within all of components of overmold 174 (see Faltys Fig. 3A) that comprises a first component 12 and a second component 13 (see Reischl Figs. 1-3).

22. As to Claims 12-17, 39-42, and 52, Reischl discloses an edge of first component 12 that provides a sloped interface with a surface of a patient 15 and an angle between the edge and the surface of the patient (see Reischl Fig. 1). The Examiner takes the position that this angle is the unmarked angle supplementary to the marked angle in Reischl Fig. 1. Reischl differs from

Claims 12-17 and 39-41 in that the angle is not specified to be greater than 90 degrees, within a range from 120 and 150 degrees, or approximately equal to 135 degrees. It would have been obvious to one having ordinary skill in the art at the time of the invention to make the angle created by the sloped interface and the surface of the patient greater than 90 degrees, within a range from 120 and 150 degrees, or approximately equal to 135 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges or discovering an optimum value of a result effective variable involves only routine skill in the art.

23. As to Claim 18-19 and 43, Reischl discloses an overmold that is concave such that the overmold conforms substantially to a cranium of a patient (see Reischl Fig. 5 and column 2, lines 1-7). It is inherent that the overmold is molded prior to implantation to conform substantially to a cranium of a patient (see Reischl Abstract).

24. As to Claim 31 and 45, Reischl discloses that the implantable medical device disclosed may be used as any other implant, especially those applicable for implantation in the mastoid region of the skull (see Reischl column 3, lines 5-9). The Examiner takes the position that, "any other implant applicable for implantation in the mastoid region of the skull", encompasses devices for administering neurostimulation therapy to a patient.

25. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys in view of Berrang et al. (U.S. 6,358,281) (herein Berrang). Faltys differs from Claim 27 in that the overmold does not include a through-hole to receive an attachment mechanism for attaching the implantable medical device to a patient.

Berrang, however, discloses an implantable medical device 1 comprised of interconnected modules 2 and 3, each contained within a housing, and connector bridge 6 that at least partially encapsulate each of the modules (see Berrang Fig. 1). Connector bridge 6 is adapted to allow the surgeon to better fit the housing sections 2 and 3 to the curvature of the implantee's skull (see Berrang column 9, lines 55-56) via suture lines or screws so as to minimize movement of the housed sections after implantation (see Berrang column 14, lines 15-19). The Examiner takes the position that it is inherent that connector bridge comprises at least one through-hole to receive suture lines or screws for attaching the device to the skull. The Examiner also takes the position that the connector bridge of Berrang is synonymous with the overmold of Faltys because they both at least partially encapsulate the modules and are both flexible. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the overmold of Faltys in view of Berrang to include a through-hole to receive an attachment mechanism for attaching the implantable medical device to a patient so as to minimize movement of the housed modules after implantation.

26. As to Claim 28, Berrang discloses that the bridge structure 6 contains pliable metal (such as gold or platinum) so to substantially allow a bent shape on insertion (see Berrang column 9, lines 51-54). Berrang also discloses that biocompatible metal such as gold or platinum are radio-opaque markers that can be identified in vivo, using medical imaging techniques known in the art (see Berrang column 10, lines 49-56).

27. Claims 44 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys in view of Reischl and Berrang. The previously modified Faltys reference differs from Claims 44 and 45 in that at least one of the first and second materials of the overmold does not include a

through-hole to receive an attachment mechanism for attaching the implantable medical device to a patient.

Berrang, however, discloses an implantable medical device 1 comprised of interconnected modules 2 and 3, each contained within a housing, and connector bridge 6 that at least partially encapsulate each of the modules (see Berrang Fig. 1). Connector bridge 6 is adapted to allow the surgeon to better fit the housing sections 2 and 3 to the curvature of the implantee's skull (see Berrang column 9, lines 55-56) via suture lines or screws so as to minimize movement of the housed sections after implantation (see Berrang column 14, lines 15-19). The Examiner takes the position that it is inherent that connector bridge comprises at least one through-hole to receive suture lines or screws for attaching the device to the skull. The Examiner also takes the position that the connector bridge of Berrang is synonymous with the overmold of Faltys because they both at least partially encapsulate the modules and are both flexible. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the overmold of Faltys in view of Reischl and Berrang to include a through-hole to receive an attachment mechanism for attaching the implantable medical device to a patient so as to minimize movement of the housed modules after implantation.

28. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys in view of Rosenman et al. (U.S. 2003/0073972) (herein Rosenman). Faltys differs from Claim 29 in that the overmold is not impregnated with a therapeutic agent.

Rosenman, however, discloses an implantable medical device that may be coated, filled, or made of a drug or drug eluting compound, or drug delivery matrix of any composition in order

to deliver a therapeutic agent to the implantation site (see Rosenman Abstract). The Examiner takes the position that the device of Rosenman is analogous to the claimed invention in that both are implantable medical devices that have a coating comprising a therapeutic device. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Faltys in view of Rosenman to include an overmold impregnated with a therapeutic device to deliver a therapeutic agent to the implantation site.

Conclusion

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Casey (U.S. 2003/0004546) discloses an implantable medical device made of photocells 180 enclosed in a case laminated into the shape of a gradual curve that duplicates the curvature of the cranium and conforms to the implantation site. The case, or overmold, comprises a first component and a second component and is capable of being sutured to a cranium. Voltz et al. (U.S. 5,755,743) (herein Voltz) discloses an implantable unit with at least one lead connection module for connection of electrical or electronic device, which is hermetically sealed within a housing. Schindler et al. (U.S. 5,477,855) discloses an implantable device comprising a shield that provides cover for internal conductors and protects them against being dislodged or moved by scratching, physical activity, skin pressure, or other circumstances. Pless et al. (U.S. 6,618,623) discloses a ferrule for retaining an implatable device within a cranial opening of a patient.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert E. Pezzuto
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Jessica L. Reidel